

## § 488.2

*Provider of services* or *provider* means a hospital, critical access hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or provider of outpatient physical therapy or speech pathology services.

*Rate of disparity* means the percentage of all sample validation surveys for which a State survey agency finds noncompliance with one or more Medicare conditions and no comparable condition level deficiency was cited by the accreditation organization, where it is reasonable to conclude that the deficiencies were present at the time of the accreditation organization's most recent surveys of providers or suppliers of the same type.

*Example:* Assume that during a validation review period State survey agencies perform validation surveys at 200 facilities of the same type (for example, ambulatory surgical centers, home health agencies) accredited by the same accreditation organization. The State survey agencies find 60 of the facilities out of compliance with one or more Medicare conditions, and it is reasonable to conclude that these deficiencies were present at the time of the most recent survey by an accreditation organization. The accreditation organization, however, has found deficiencies comparable to the condition level deficiencies at only 22 of the 60 facilities. These validation results would yield  $((60-22)/200)$  a rate of disparity of 19 percent.

*Reasonable assurance* means that an accreditation organization has demonstrated to CMS's satisfaction that its requirements, taken as a whole, are at least as stringent as those established by CMS, taken as a whole.

*State* includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

*State survey agency* means the State health agency or other appropriate State or local agency used by HFCA to perform survey and review functions for Medicare.

*Substantial allegation of noncompliance* means a complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that, if substantiated, would affect the health and safety of patients and raises

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doubts as to a provider's or supplier's noncompliance with any Medicare condition.

*Supplier* means any of the following: Independent laboratory; portable X-ray services; physical therapist in independent practice; ESRD facility; rural health clinic; Federally qualified health center; chiropractor; or ambulatory surgical center.

*Validation review period* means the one year period during which CMS conducts a review of the validation surveys and evaluates the results of the most recent surveys performed by the accreditation organization.

[53 FR 22859, June 17, 1988, as amended at 54 FR 5373, Feb. 2, 1989; 56 FR 48879, Sept. 26, 1991; 57 FR 24982, June 12, 1992; 58 FR 30676, May 26, 1993; 58 FR 61838, Nov. 23, 1993; 62 FR 46037, Aug. 29, 1997; 71 FR 68230, Nov. 24, 2006]

### § 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

- 1128—Exclusion of entities from participation in Medicare.
- 1128A—Civil money penalties.
- 1814—Conditions for, and limitations on, payment for Part A services.
- 1819—Requirements for SNFs.
- 1861(f)—Requirements for psychiatric hospitals.
- 1861(z)—Institutional planning standards that hospitals and SNFs must meet.
- 1861(ee)—Discharge planning guidelines for hospitals.
- 1861(ss)(2)—Accreditation of religious non-medical health care institutions.
- 1864—Use of State survey agencies.
- 1865—Effect of accreditation.
- 1880—Requirements for hospitals and SNFs of the Indian Health Service.
- 1883—Requirements for hospitals that provide SNF care.
- 1902—Requirements for participation in the Medicaid program.
- 1913—Medicaid requirements for hospitals that provide NF care.
- 1919—Medicaid requirements for NFs.

[60 FR 50443, Sept. 29, 1995, as amended at 64 FR 67052, Nov. 30, 1999]

### § 488.3 Conditions of participation; conditions for coverage; and long-term care requirements.

(a) *Basic rules.* In order to be approved for participation in or coverage under the Medicare program, a prospective provider or supplier must: